UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 Master File No. 1:01-CV-12257-PBS Sub-Category Case No. 1:08-CV-11200
THIS DOCUMENT RELATES TO: *United States ex rel. Linnette Sun and Greg Hamilton, Relators,* *v.* *Baxter Healthcare Corporation.*	Judge Patti B. Saris

LOCAL RULE 56.1 STATEMENT OF MATERIAL FACTS SUPPORTING BAXTER HEALTHCARE CORPORATION'S MOTION FOR PARTIAL SUMMARY JUDGMENT

Pursuant to Rule 56 of the Federal Rules of Civil Procedure and Local Rule 56.1, Defendant Baxter Healthcare Corporation ("Baxter") submits this statement of material facts for which there can be no dispute in support of its Motion for Partial Summary Judgment.

I. THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, THE CENTERS FOR MEDICARE AND MEDICAID SERVICES, AND THE OFFICE OF THE INSPECTOR GENERAL

1. The Department of Health and Human Services ("HHS"), through—first the Health Care Financing Administration ("HCFA") and now the Centers for Medicare and Medicaid Services ("CMS")—administers the Medicare program, which is a system of health insurance for persons over the age of 65 years and for persons who are disabled, created under Title XVIII of the Social Security Act. 42 U.S.C. § 1395, *et seq.*; *see also* Key Milestones in CMS Programs, attached to the Declaration of Shamir Patel as Exhibit (hereinafter "Patel Decl. Ex.") A, at unnumbered p. 1.

2. CMS also administers the Medicaid program, which provides health care benefits for certain groups, including the poor and disabled. Each State's plan for medical assistance is approved by the United States Secretary of Health and Human Services. 42 U.S.C § 1396 *et seq.*; *id.* § 1396-1; *see also* Patel Decl. Ex. A, at unnumbered p. 1.

3. The HHS Office of the Inspector General ("OIG") is the largest inspector general's office in the Federal Government and is dedicated to combating fraud, waste, and abuse and to improving the efficiency of HHS programs. A majority of the OIG's resources goes toward the oversight of Medicare and Medicaid. *See* Department of Health and Human Services, Office of Inspector General, About Us, *available at* http://oig.hhs.gov/about-oig/about-us/index.asp (last visited Oct. 4, 2011). The OIG was established in 1976, in part as a response to congressional hearings and investigations that had uncovered deficiencies, fraud, and waste in the Medicaid program. Excerpt from DEPARTMENT OF HEALTH AND HUMAN SERVICES, OFFICE OF INSPECTOR GENERAL, PROTECTING PUBLIC HEALTH AND HUMAN SERVICES PROGRAMS: A 30-YEAR RETROSPECTIVE (2006), Patel Decl. Ex. B, at 7. The OIG, originally part of the Department of Health, Education, and Welfare ("HEW"), became the HHS OIG in 1980. *Id.* The "OIG has worked extensively with CMS * * * to identify vulnerabilities in Medicare and Medicaid and recommend improvements, to quantify and reduce improper payments, and to pursue instances of fraud and abuse." *Id.* at 16.

II. GOVERNMENT KNOWLEDGE AND APPROVAL OF THE USE OF BLOOD-CLOTTING THERAPY AWPs AS A BASIS FOR REIMBURSEMENT

A. Background: Increasing General Government Knowledge

4. The Government's knowledge of Average Wholesale Price ("AWP") spreads stretches back as far as the 1970s. For example:

a. A November 27, 1974 HEW Notice of Proposed Rule Making stated: "*Most States use average wholesale price,* Red Book data, Blue Book

data, survey results or similar standard costs. *Such standard prices are frequently in excess of actual acquisition costs to the retail pharmacist*." Department of Health, Education, and Welfare Proposed Rule Making, *Reimbursement of Drug-Cost—Medical Assistance Program*, Notice of Proposed Rule Making, 39 Fed. Reg. 41480 (Nov. 27, 1974) (codified at 45 C.F.R. Part 250), Patel Decl. Ex. C (emphasis added).

b. A December 13, 1977 HCFA (now CMS) Action Transmittal to the States stated: "*the Department is not convinced that those states which continue to reimburse at average wholesale price (AWP) * * * have made a real effort to approach [actual acquisition cost]*." HEALTHCARE FINANCING ADMINISTRATION, HCFA Action Transmittal No. HCFA-AT-77-113 (MMB), Medicaid-Formula for Determining EAC for Drugs, LIMITATION ON PAYMENT OR REIMBURSEMENT FOR DRUGS – FORMULA FOR DETERMINING ESTIMATED ACQUISITION COST, *reprinted in* Medicare and Medicaid Guide (CCH) § 28,714 (1977), Patel Decl. Ex. D (emphasis added).

5. The Government continued investigating and reporting on AWP spreads throughout the 1980s. For example:

a. A 1984 OIG Report that reviewed State Medicaid reimbursement found that AWPs were not adequate estimates of the prices providers pay for drugs because "*[w]ithin the pharmaceutical industry, AWP means non-discounted list price*. Pharmacies purchase drugs at prices that are discounted significantly below AWP or list price." DEPARTMENT OF HEALTH AND HUMAN SERVICES, OFFICE OF THE INSPECTOR GENERAL, CHANGES TO THE MEDICAID PRESCRIPTION DRUG PROGRAM COULD SAVE MILLIONS, Audit Control No. 06-40216 (Sept. 1984), Patel Decl. Ex. E, at 3 (emphasis added). It went on to state: "*AWP cannot be the best – or even an adequate – estimate of the prices providers generally are paying for drugs.*" *Id.* at 22 (emphasis added).

b. A September 1, 1984 HHS Medicaid Action Transmittal to the States reported: "Pharmacies purchase drugs at prices that are discounted significantly below AWP or list price * * *. *The use of AWP in determining Medicaid reimbursement for drugs has been a problem that HCFA has recognized for some time*." DEPARTMENT OF HEALTH AND HUMAN SERVICES, OFFICE OF INSPECTOR GENERAL, Medicare Action Transmittal No. 84-12, MEDICAID – LIMITATION ON PAYMENT FOR DRUGS, *reprinted in* Medicare and Medicaid Guide (CCH) § 34,157 (1984), Patel Decl. Ex. F, at unnumbered pp. 2-3 (emphasis added).

c. A September 29, 1989 Memorandum from the OIG to the Acting Administrator of the HCFA stated: "*[W]e continue to believe that AWP is not a reliable price to be used as a basis for making reimbursements for*

either the Medicaid or Medicare programs." Memorandum from Richard P. Kusserow, Inspector General, Department of Health and Human Services, to Louis B. Hays, Acting Administrator, Health Care Financing Administration (Sept. 29, 1989), Patel Decl. Ex. G, at 7 (emphasis added); *see also* OIG Report Concerning Medicaid and Medicare Reimbursement for Drugs, Medicare and Medicaid Guide (CCH), A-06-89-00037, § 38,215 (1990), Patel Decl. Ex. H, at 7.

6. Numerous other OIG reports from 1992 through 1997 discuss AWP spreads, as catalogued in the report of this Court's appointed expert, Dr. Ernst R. Berndt. *See, e.g.*, Attachment B to Report of Independent Expert Professor Ernst R. Berndt to Judge Patti B. Saris, *In re Pharm. Indus. Average. Wholesale Price Litig.*, No. 1:01-CV-12257 (D. Mass. Feb. 9, 2005), Patel Decl. Ex. I, at 160-61. These reports include:

a. A May 1996 OIG Report on physician-administered drugs reimbursed by Medicare, which concluded that AWP is not a reliable indicator of the cost of drugs to providers. DEPARTMENT OF HEALTH AND HUMAN SERVICES, OFFICE OF INSPECTOR GENERAL, APPROPRIATENESS OF MEDICARE PRESCRIPTION DRUG ALLOWANCES, OEI-03-95-00420 (May 1996), Patel Decl. Ex. J, at ii, 8.

b. A December 1997, OIG Report that stated: "The published AWPs that are currently being used by Medicare-contracted carriers to determine reimbursement bear little or no resemblance to actual wholesale prices that are available to the physician and supplier communities that bill for these drugs." DEPARTMENT OF HEALTH AND HUMAN SERVICES, OFFICE OF INSPECTOR GENERAL, EXCESSIVE MEDICARE PAYMENTS FOR PRESCRIPTION DRUGS, OEI-03-97-00290 (Dec. 1997), Patel Decl. Ex. K, at ii.

7. In June of 1997, leading up to the passage of the Balanced Budget Act of 1997, the Committee on the Budget of the House of Representatives issued a report that stated: "The Inspector General for the Department of Health and Human Services has found evidence that over the past several years Medicare has paid significantly more for drugs and biologicals than physicians and pharmacists pay to acquire such pharmaceuticals. For example, the Office of Inspector General reports that Medicare reimbursement for the top 10 oncology drugs ranges from 20 percent to nearly 1000 percent per dosage more than acquisition costs." *See In re*

Pharm. Indus. Average Wholesale Price Litig., 491 F. Supp. 2d 20, 77-78 (D. Mass. 2007), *aff'd*, 582 F.3d 156 (1st Cir. 2009), *cert. dismissed*, 131 S. Ct. 60 (2010).

8. The President's 1997 budget contained a legislative proposal that would have based payment on the lower of the billed charge or the actual acquisition cost ("AAC") for the drug of the physician or supplier billing Medicare. Congress rejected this proposal. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d at 42; *see also* The President's Weekly Radio Address, 33 Weekly Comp. Pres. Doc. 51 (Dec. 13, 1997), Patel Decl. Ex. L, at 2034.

9. Instead, in August 1997, Congress passed the Balanced Budget Act of 1997 ("BBA"), which set the Medicare reimbursement rate at 95% of AWP. *See* Pub. L. No. 105-33, 111 Stat. 251 (1997). Congress did not define "AWP" or direct the manner in which it was to be determined.

10. On December 13, 1997, the President of the United States addressed the Nation regarding waste, fraud, and abuse in the Medicare system stating:

> Last week, the Department of Health and Human Services confirmed that our Medicare program has been systematically overpaying doctors and clinics for prescription drugs * * *. *[T]hese overpayments occur because Medicare reimburses doctors according to the published average wholesale price – the so-called sticker price – for drugs. Few doctors, however, actually pay the full sticker price. * * * That's why I'm sending to Congress again the same legislation I sent last year* – legislation that will ensure that doctors are reimbursed no more, and no less, than the price they themselves pay for the medicines they give Medicare patients. While a more modest version of this bill passed last summer, the savings to taxpayers is not nearly enough.

Patel Decl. Ex. L, at 2033-34 (emphasis added).

11. Once again, Congress did not take up the President's recommendation, and the relevant portions of the BBA and resulting regulations stayed in effect until Congress passed the Medicare Modernization Act in 2003.

12. On August 10, 2001, the OIG issued a Report to CMS stating: "*Based on our review, we have determined that there is a significant difference between pharmacy acquisition cost for brand name drugs and AWP.*" DEPARTMENT OF HEALTH AND HUMAN SERVICES, OFFICE OF INSPECTOR GENERAL, MEDICAID PHARMACY – ACTUAL ACQUISITION COST OF BRAND NAME PRESCRIPTION DRUG PRODUCTS, A-06-00-00023 (Aug. 2001), Patel Decl. Ex. M, at 5 (emphasis added).[1]

13. On September 2001, the Government Accountability Office ("GAO") submitted a report to Congress stating: "Medicare's method for establishing drug payment levels is flawed. *In tying its payment to AWP, a price that may be neither an average nor what wholesalers charge, Medicare has been paying much more than providers' likely acquisition cost.*" U.S. GOVERNMENT ACCOUNTABILITY OFFICE, GAO-01-1118, MEDICARE – PAYMENTS FOR COVERED OUTPATIENT DRUGS EXCEED PROVIDERS' COST (Sept. 2001), Patel Decl. Ex. O, at 24-25 (emphasis added).

14. On September 21, 2001, the House Committee on Energy and Commerce, Subcommittee on Health held a hearing on Medicare Drug Reimbursements. Representative James C. Greenwood stated:

> [U]nder current Federal law and regulations, Medicare is paying for drugs at AWP. *AWP, or average wholesale price, could also be an acronym for 'ain't what's paid.'* It is quite clear that despite its name, AWP is not the average wholesale price at which these drugs are sold to health care providers or anything close to it.

Excerpt from *Medicare Drug Reimbursements: A Broken System for Patients and Taxpayers*, Before the H. Subcomm. on Oversight and Investigations of the H. Comm. on Energy and

[1] A September 16, 2002 OIG Report to CMS noted that its August 10, 2001 Report included single source drugs. DEPARTMENT OF HEALTH AND HUMAN SERVICES, OFFICE OF INSPECTOR GENERAL, MEDICAID PHARMACY – ADDITIONAL ANALYSIS OF THE ACTUAL ACQUISITION COST OF PRESCRIPTION DRUG PRODUCTS, A-06-02-00041 (Sept. 2002), Patel Decl. Ex. N, at 5.

Commerce, 107th Cong. (2001) (statement of Rep. James C. Greenwood, Member, H. Subcomm. on Oversight and Investigations), Patel Decl. Ex. P, at 3 (emphasis added).

15. On March 14, 2002, the OIG issued a Report to CMS that addressed AWP/AAC discrepancies and stated: "*[T]here is a significant difference between pharmacy acquisition cost for generic drugs and AWP*." DEPARTMENT OF HEALTH AND HUMAN SERVICES, OFFICE OF INSPECTOR GENERAL, MEDICAID PHARMACY – ACTUAL ACQUISITION COST GENERIC PRESCRIPTION DRUG PRODUCTS, A-06-01-00053 (Mar. 14, 2002), Patel Decl. Ex. Q, at 6 (emphasis added).

16. Also on March 14, 2002, Thomas A. Scully, Administrator of CMS, provided testimony on reimbursement and access to prescription drugs under Medicare Part B to the Senate Finance Committee, Subcommittee on Health stating:

> *This Committee, CMS, the Department's Office of the Inspector General (IG), and others have long recognized the shortcomings of AWP as a way for Medicare to reimburse for drugs*. The IG has published numerous reports showing that true competitive market prices for the top drugs billed to the Medicare program by physicians * * * were actually significantly less than the AWP reported in the *Red Book* and other publications.

Excerpt from *Reimbursement & Access to Prescription Drugs Under Medicare Part B*, Before the S. Finance Comm., Subcomm. on Health, 107th Cong. (2002) (statement of Thomas A. Scully, Administrator, Centers for Medicare and Medicaid Services, Washington, DC), Patel Decl. Ex. R, at 5 (emphasis added).

17. On October 3, 2002, George Reeb, Assistant Inspector General, Centers for Medicare and Medicaid Audits, provided testimony to the House Committee on Ways and Means, Subcommittee on Health stating,

> Over the past 5 years, the OIG has issued a number of reports, all of which have reached the conclusion that Medicare and its beneficiaries pay too much for prescription drugs * * *. *Although this hearing pertains to Medicare, I would like*

> *to mention our work in the Medicaid program because it confirms that the average wholesale price (AWP) is not a realistic basis for drug reimbursements.*

Excerpt from *Medicare Payments for Currently Covered Prescription Drugs*, Before the H. Comm. on Ways and Means, H. Subcomm. on Health, 107th Cong. (2002) (statement of George Reeb, Assistant Inspector General, Centers for Medicare and Medicaid Audits, Department of Health and Human Services, Office of Inspector General), Patel Decl. Ex. S, at 2-3 (emphasis added).

18. Numerous other OIG reports from 1997 through 2002 discuss AWP spreads, as catalogued in the report of this Court's appointed expert, Dr. Ernst R. Berndt. *See* Patel Decl. Ex. I, at 161-64.

19. This Court has ruled that "[b]y 2001, there was a perfect storm of information that reflected the size of the spreads, largely because of the compelling information collected by the HHS Office of Inspector General." *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d at 41.

B. <u>Specific Knowledge As To The Spreads For Blood-Clotting Factors</u>

20. No fewer than 38 AWP complaints, all alleging essentially the same AWP inflation scheme, had been filed against Baxter before Relators filed their 2005 lawsuit. *See* List of 38 Cases filed against Baxter prior to April 22, 2005, Patel Decl. Ex. T.

21. Each one of these complaints provided the Government knowledge of AWP spreads relating to Baxter's drugs. *See* 31 U.S.C. § 3730(b)(2).

22. In early 2000, the Department of Justice ("DOJ") and the National Association of Medicaid Fraud Control Units ("NAMFCU") provided an alternative source of AWP data—so-called DOJ AWPs—to First DataBank, Inc. ("FDB"), which, in turn, provided these to state Medicaid programs on May 1, 2000. *See* DEPARTMENT OF HEALTH AND HUMAN SERVICES,

HEALTH CARE FINANCING ADMINISTRATION, AN ADDITIONAL SOURCE OF AVERAGE WHOLESALE PRICE DATA IN PRICING DRUGS AND BIOLOGICALS COVERED BY THE MEDICARE PROGRAM, AB-00-86 (Sept. 8, 2000), Patel Decl. Ex. U, at 1.

23. DOJ AWPs were provided for Baxter's antihemophilic blood-clotting therapy Recombinate, a therapy that, like Advate, treats a clotting Factor VIII deficiency. *Id.* at 18; *see also infra* SOF ¶ 34. However, the HCFA wrote:

> *[W]e have some concern about access to care related to the DOJ's wholesale prices for * * * 3 clotting factors (Attachment 2),*[2] *due to other Medicare payment policies associated with the provision of these drugs for the treatment of * * * hemophilia*. Therefore, you are not to consider at this time using the DOJ data for these drugs (Attachment 2) to establish your Medicare allowances* * *. *For the drugs shown in Attachment 2, use your usual source of average wholesale prices in your next quarterly update*.

Patel Decl. Ex. U, at 2 (emphasis added).

24. Similarly, on September 8, 2000, Nancy-Ann Min DeParle, Administrator of HCFA, wrote a letter to members of Congress in which she wrote: "*Medicare payments for services related to the provision of chemotherapy drugs and clotting factors used to treat hemophilia and similar disorders are inadequate.*" *See* Letter from Congressman Thomas Bliley, Chair of the H. Commerce Comm., to Nancy-Ann Min DeParle, HCFA Administrator (Sept. 25, 2000), Patel Decl. Ex. V, at 3 (emphasis added).

25. A September 25, 2000 letter from Congressman Tom Bliley, Chair of the House Commerce Committee, responded to Ms. DeParle, and discussed AWP spreads. *Id.* at 1. He included Bayer documents that addressed Baxter's AWPs for an antihemophilic factor therapy. *Id.* at 7 and Attachment 6, at unnumbered p. 3. Mr. Bliley wrote: "*HCFA has known for many*

[2] Attachment 2 contained a list of chemotherapy drugs and clotting Factor VIII therapies, including: Baxter's Recombinate; Bayer's Koate HP and Kogenate; and Centeon's Bioclate, Helixate, and Monclate-P. *See id.* at 18-19.

years that it was paying inflated prices for certain drugs." *Id.* at 1 (emphasis added). He also wrote: "Your actions also demonstrate that HCFA already possesses – and indeed has always possessed – the authority to remedy this problem itself, without need of new legislation or any other Congressional action." *Id.* at 2. With respect to HCFA's position that Medicare payments were inadequate for the provision of services related to blood-clotting therapies, he wrote: "If this problem does indeed exist, it is one that HCFA should have been aware of and remedied long before I first wrote to Secretary Shalala, rather than *tacitly allowing an alleged cross-subsidization between drug reimbursement rates and practice expenses to continue to exist*." *Id.* at 3 (emphasis added).

26. In September 2001, the OIG issued a report which stated:

> Over the last several years, the OIG has produced a significant body of work that clearly demonstrates the inflated nature of reported average wholesale prices. * * * *[W]e continue to believe that the current system's reliance on reported average wholesale prices as a basis for drug reimbursement is fundamentally flawed*.

DEPARTMENT OF HEALTH AND HUMAN SERVICES, OFFICE OF INSPECTOR GENERAL, MEDICAID'S USE OF REVISED AVERAGE WHOLESALE PRICES, OEI-03-01-00010 (Sept. 2001), Patel Decl. Ex. W, at 9 (emphasis added). This report described the State Medicaid agencies' use of revised average wholesale prices created in conjunction with the DOJ, the NAMFCU, and FDB. It noted:

> Several States reported that the revised average wholesale prices are closer to true acquisition cost; therefore, subtracting a percentage discount may actually make the reimbursement amount fall below a provider's acquisition cost. *They remarked that if providers were reimbursed below cost, they would simply stop providing these drugs, which could limit a patient's access to care*.

Id. at 5 (emphasis added). However, the report further noted:

> Forty-three States reported receiving complaints about the revised prices * * * . Some hemophilia providers claimed that they would be unable to continue treating Medicaid recipients unless the prices for blood factors were raised. *These*

> *complaints were instrumental in two States' [D.C. and Indiana, id. at 10-11] decisions to discontinue the use of the revised prices for blood-factor products, and have caused other States to contemplate the same action.* * * * The majority of the 19 States that are not using the revised prices felt that the prices may be too low, especially when a percentage discount is subtracted.

Id. at 7 (emphasis added).

27. In response to an earlier draft of this report, on August 20, 2001, Ruben J. King-Shaw, Jr., Deputy Administrator and Chief Operating Officer, CMS, wrote to the OIG: *"Since the regulations and relevant state plans authorize payment for drugs based on AWPs, regardless of whether those prices are inflated, we have concerns with the statement that states and Medicaid have 'overpaid' for drugs."* *Id.* Appendix B, at 13 (emphasis added). He therefore recommended deleting those sentences. *Id.*

28. A January 2003 GAO report reported that hemophilia treatment centers and homecare companies were obtaining prices from manufacturers of blood-clotting therapies that were significantly below AWPs. U.S. GOVERNMENT ACCOUNTABILITY OFFICE, GAO-03-184, MEDICARE: PAYMENT FOR BLOOD CLOTTING FACTOR EXCEEDS PROVIDERS' ACQUISITION COST (2003), Patel Decl. Ex. X, at 3, 10. This report includes the recommendation, "to reflect costs more accurately," that the Administrator establish a separate payment for the costs of delivering the therapies to Medicare beneficiaries. *Id.* at 4. It notes that "[c]lotting factor's biological properties and complex dosing protocols contribute to dispensing costs in the form of inventory management, storage, and shipping. In addition, the cost of ancillary supplies that are necessary for infusing clotting factor, such as needles, syringes, and tourniquets, is not reimbursed by Medicare." *Id.* This report also notes that hemophilia treatment centers are federally funded facilities that provide medical care to persons with hemophilia, *id.* at 2 n.4, and that homecare companies are also known as "specialty pharmacies," *id.* at 2 n.5.

29. On June 25, 2003, the Medicare Modernization Act ("MMA") was introduced to Congress. *See* 149 Cong. Rec. H5928-01, 2003 WL 21473659 (2003).

30. On July 15, 2003, the House Committee on Ways and Means issued a report, *Medicare Prescription Drug and Modernization Act of 2003*, H.R. Rep. No. 108-178, pt. 2, at 197-198 (2003), stating: *"AWPs are not grounded in any real market transaction, and do not reflect the actual price paid by purchasers. Congress has long recognized AWP is a list price and not a measure of actual prices."* *In re Pharm. Indus. Average Wholesale Price Litig.*, 460 F. Supp. 2d 277, 283 (D. Mass. 2006) (emphasis added).

31. The MMA went into effect December 8, 2003. *See* Pub. L. No. 108-173, 117 Stat. 2066 (2003).

32. Despite the known AWP spreads, the MMA continued to allow the use of AWPs. *See* 42 U.S.C. § 1395u(o). The MMA provided for a shift from 95% to 85% of AWP in 2004 and then to 106% of "average sales price" in 2005. *Id.* § 1395u(o)(4). The MMA made an explicit exception for blood-clotting therapies and allowed them to continue to be reimbursed at 95% of AWP through Dec. 31, 2004. *Id.* § 1395u(o)(1)(A)(ii), (o)(4)(A).

33. As this Court concluded, "[t]he statute and the legislative history [of the MMA] indicate that by 2003, [AWP] had become a term of art. At that point, Congress clearly did understand AWP was different than average sales price and was not reflective of actual prices in the marketplace." *In re Pharm. Indus. Average Wholesale Price Litig.*, 460 F. Supp. 2d at 288.

III. ADVATE

34. Advate is an antihemophilic recombinant blood-clotting factor therapy used to treat hemophilia A. Approval Letter – Advate, from Department of Health and Human Services, Food and Drug Administration to Baxter Healthcare Corporation (July 25, 2003), Patel Decl. Ex.

Y; Advate Fact Sheet, Patel Decl. Ex. Z, at unnumbered p. 2. Hemophilia A results from a deficiency in an individual's clotting Factor VIII. *See* Patel Decl. Ex. Z at unnumbered p. 2.

35. Advate is an innovative blood-clotting therapy that was the first to be made without any added human or animal plasma proteins, which eliminated the risk of infections. *See Baxter Healthcare Corp. v. Weeks*, 643 F. Supp. 2d 111, 113 (D.D.C. 2009).

36. In late July 2003, Advate was approved by the FDA. Patel Decl. Ex. Y.

37. On August 20, 2003, two months after the MMA was introduced in Congress and less than four months before it became law, Baxter began selling Advate in the United States. *See* Declaration of Larry Guiheen, Patel Decl. Ex. AA, ¶ 9.

38. When Advate first came to the market, CMS classified it as an antihemophilic factor recombinant therapy similar to other antihemophilic therapies already on the market. *See Baxter Healthcare Corp. v. Weeks*, 643 F. Supp. 2d at 113-14, 118.

39. On August 27, 2004, CMS issued Transmittal 109 to its contractors governing payment for Advate from its July 25, 2003 FDA approval through December 31, 2004, and requiring that Advate be assigned to Healthcare Common Procedure Coding System ("HCPCS") code J7192 with several other clotting factors rather than to a separate billing code. DEPARTMENT OF HEALTH AND HUMAN SERVICES, CENTERS FOR MEDICARE & MEDICAID SERVICES, TRANSMITTAL 109, CHANGE REQUEST 3331, BILLING INSTRUCTIONS FOR ADVATE RAHF-PFM ON MEDICARE CLAIMS (Aug. 27, 2004), Patel Decl. Ex. BB; *see also Baxter Healthcare Corp. v. Weeks*, 643 F. Supp. 2d at 113-14.

40. Although Transmittal 109 had an implementation date of September 27, 2004, the Transmittal indicated that it was to be effective retroactive to July 25, 2003. Patel Decl. Ex. BB.

41. At the time of Advate's release, no less than five other Factor VIII recombinant clotting factors were assigned HCPCS code J7192, including Recombinate. Excerpt from *Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005*; Proposed Rule, 69 Fed. Reg. 47488, 47566 (Aug. 5, 2004), Patel Decl. Ex. CC, at Table 28.—Drug Pricing Table Used for Payment Impacts.

42. Beginning January 1, 2005, as directed by the MMA, CMS established a separate payment, in addition to the Average Sale Price ("ASP")-based reimbursement for the blood-clotting therapies, for items and services associated with therapies in accordance with 42 U.S.C. § 1395u(o)(5)(C). Blood Clotting Factor Furnishing Fee from 2005 through 2011, Patel Decl. Ex. DD.

IV. THE SETTLEMENT OF THE VEN-A-CARE FEDERAL *QUI TAM*

43. On October 5, 2011, Baxter settled both the federal Ven-A-Care *qui tam* and a Florida Ven-A-Care *qui tam* with the express written consent of both the United States and the State of Florida. October 5, 2011 Settlement Agreement and Release, Patel Decl. Ex. EE.

44. Paragraph III.7 of the October 5, 2011 Settlement Agreement and Release ("Settlement Agreement and Release") provides a release to Baxter for any claim "which has been asserted, could have been asserted, or could be asserted in the future under any source of law * * * arising from any of the Covered Conduct." *Id.* ¶ III.7.

45. Paragraph II.E broadly defines "Covered Conduct" in terms of both the *period* of covered activities and the *subject matter* of those activities. *Id.* ¶ II.E. The period of time covered by the release extends from June 23, 1989 through October 5, 2011, the date of the agreement's execution. *Id.* ¶ III.21.

46. The covered subject matter includes all manner of false claims and pricing manipulation allegations covering a full range of suggested, listed, and reported prices for any "Baxter Covered Drug." *Id.* ¶ II.E.-F.

47. "Baxter Covered Drug" is defined to include "any and all drugs manufactured, marketed and/or sold by or on behalf of any Baxter Party * * * including, without limitation, Baxter Covered Drugs with Labeler Codes 00338 and 00944." *Id.* ¶ II.E.

48. Labeler Code 00944 covers the blood-clotting therapies Recombinate and Advate. *See* CMS List of Blood Clotting Factors dated 5/2/2011, downloaded from https://www.cms.gov/Reimbursement/downloads%5Clistofbloodclottingfactors.pdf (last visited Oct. 5, 2011), Patel Decl. Ex. FF.

49. The release specifically encompasses allegations that "one or more Baxter Parties knowingly set, reported, and/or maintained, or caused to be set, reported, and/or maintained, false, fraudulent, and/or inflated prices, including, without limitation, Average of Suggested Wholesale Price to Pharmacy, Average Wholesale Price, AWP, Suggested Wholesale Price, SWP, Price to Wholesaler and/or Distributor, Direct Price to Pharmacy, Central Purchase Price to Chain (such as Warehouse Price), Institutional or Other Contract Price (Nursing Home, Home Health Care), Other Price, Suggested List Price, List Price, Wholesale Acquisition Cost, WAC, Wholesale Net Price, Direct Price, DP, Wholesale Direct Price and/or Net Direct Price, and/or other prices reported by one or more of the Baxter Parties or published by any compendia (e.g., Redbook, First Databank)." Patel Decl. Ex. EE, ¶ II.E.

50. The Settlement Agreement and Release contains exceptions designed to protect the United States' interest in preserving its ability to bring claims in a wide range of areas – such as, for example, claims for injury to real or personal property. *Id.* ¶ III.10.

51. The United States has expressly concluded that $25 million that it received in connection with the settlement was "fair, adequate, and reasonable as to the United States under all the circumstances." Excerpt from Consent of the United States of America to the Relators' Dismissal with Prejudice of Claims Pursuant to 31 U.S.C § 3730(b)(1), Patel Decl. Ex. GG.

52. On October 17, 2005, this Court dismissed with prejudice the Ven-A-Care claims against Baxter, "[c]onsistent with the terms of, and as limited by, the Settlement Agreement and Release." Order of Dismissal with Prejudice of Certain Claims Against Baxter Defendants, Patel Decl. Ex. HH.

Dated: October 19, 2011

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CERTIFICATE OF SERVICE

I hereby certify that I, Shamir Patel, an attorney, electronically filed the foregoing LOCAL RULE 56.1 STATEMENT OF MATERIAL FACTS SUPPORTING BAXTER HEALTHCARE CORPORATION'S MOTION FOR PARTIAL SUMMARY JUDGMENT with the Clerk of the Court for the District of Massachusetts using the Court's CM/ECF system on October 19, 2011. I also caused a true and correct copy of the foregoing document to be delivered to all counsel of record by electronic service via LexisNexis File & Serve, for posting and notification to all parties.

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